MEDICAL PROPELLANT HFO-1234ze(E), GMP

TECHNICAL DATA SHEET

Solstice

MEDICAL PROPELLANT
HFO-1234ZE(E), GMP

HFO-1234ze(E) is a non-flammable aerosol propellant that has ultra-low global warming potential (GWP) and very low photochemical reactivity. Its full chemical name is trans-1, 3, 3, 3-tetrafluoropropene, also known as HFO-1234ze(E).

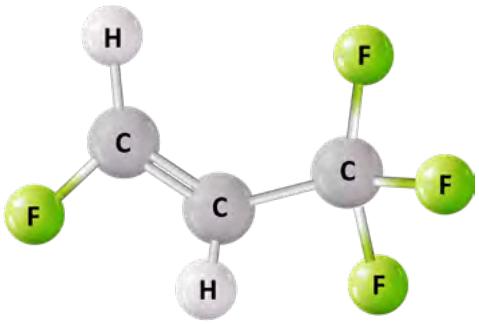

FIGURE 1:
Chemical structure of HFO-1234ze(E)

PROPELLANT PROPERTIES

Some of the physical properties of HFO-1234ze(E) are shown in Table 1. Tables 2 and 3 show vapor pressures and liquid density as a function of temperature (in SI and English units).

TABLE 1: PHYSICAL PROPERTIES OF HFO-1234ZE(E)

	HFO-1234ze(E)	
Molecular Formula	$CHF=CHCF^3$	
Molecular Weight	114 g/mol	
Boiling Point	-2.2°F	-19°C
Vapor Pressure at 70°F/21°C at 130°F/54°C	64.2 psia 161.7 psia	4.4 bar 11 bar
Liquid Density at 70°F/21°C	1.17 g/mL	
Vapor Flame Limits (Vol. % in Air) Measured at 70°F	NONE	
Solubility of Water in 1234ze at 68°F/20°C	225 ppm	
Solubility of 1234ze in Water at 68°F/20°C	373 ppm	
Dipole Moment	1.44 debye	

TABLE 2: VAPOR PRESSURE OF HFO-1234ZE(E)

°C	bar	kg/m^3	°C	bar	kg/m^3	°C	bar	kg/m^3
-15	1.20	1283	9	2.98	1214	33	6.31	1136
-12	1.36	1274	12	3.30	1204	36	6.87	1126
-9	1.53	1266	15	3.64	1195	39	7.46	1115
-6	1.73	1258	18	4.01	1186	42	8.09	1104
-3	1.94	1249	21	4.41	1176	45	8.76	1093
0	2.17	1240	24	4.84	1166	48	9.48	1082
3	2.41	1231	27	5.30	1156	51	10.02	1070
6	2.69	1223	30	5.78	1146	54	11.0	1058

TABLE 3: VAPOR PRESSURE OF HFO-1234ZE(E)

°F	psia	lbs/ft^3	°F	psia	lbs/ft^3	°F	psia	lbs/ft^3
0	15.5	80.6	45	40.6	76.1	90	89.5	71.1
5	17.4	80.1	50	44.7	75.6	95	96.8	70.5
10	19.5	79.6	55	49.1	75.0	100	105	69.9
15	21.8	79.1	60	53.8	74.5	105	113	69.3
20	24.4	78.6	65	58.8	74.0	110	122	68.6
25	27.1	78.1	70	64.2	73.4	115	131	68.0
30	30.1	77.6	75	69.9	72.8	120	141	67.3
35	33.4	77.1	80	76.0	72.3	125	151	66.6
40	36.9	76.6	85	82.5	71.68	130	161.7	65.9

* These are just some of a mosaic of properties that must be considered in identifying a suitable propellant.

FLAMMABILITY

HFO-1234ze(E) does not exhibit vapor flame limits under standard test conditions. It is therefore classified as non-flammable according to EC Testing Method A11: Flammability of Gases, as well as by the U.S. Department of Transportation (DOT) standard (tested according to ASTM E681). HFO-1234ze(E) is non-flammable in the ASTM flame projection test. HFO-1234ze(E) has also been tested and found to be non-flammable in the ignition distance test and the enclosed space ignition test (closed drum test).[1]

MISCIBILITY

HFO-1234ze(E) is miscible with other liquefied gas propellants such as HFA-134a and HFA-152a. It is also miscible with commonly used solvents such as lower alcohols, ketones, chlorinated solvents, and hydrocarbons.

Vapor pressure data for blends of HFO-1234ze(E) with other propellants are shown in Tables 4-5.

TABLE 4: VAPOR PRESSURES OF HFO-1234ZE(E)/HFA MIXTURES**

HFO-1234ze(E)/HFA-134a			HFO-1234ze(E)/HFA-152a	
Weight % 1234ze	70°F	130°F	70°F	130°F
80	71	177	70	175
60	76	189	73	182
40	80	199	75	186
20	83	207	76	189

TABLE 5: VAPOR PRESSURES OF HFO-1234ZE(E)/HFA MIXTURES**

HFO-1234ze(E)/HFA-134a			HFO-1234ze(E)/HFA-152a	
Weight % 1234ze	21°C	54°C	21°C	54°C
80	4.9	12.2	4.8	12.0
60	5.2	13.0	5.0	12.5
40	5.5	13.7	5.2	12.8
20	5.7	14.3	5.3	13.0

ENVIRONMENTAL PROPERTIES

In work done at the University of Copenhagen, the atmospheric lifetime of HFO-1234ze(E) was determined to be approximately two weeks. The GWP, which is largely a function of atmospheric lifetime, was determined to be <1 versus CO_2 on a 100-year integrated time horizon[2]. In a companion study, also at the University of Copenhagen, it was determined that the atmospheric degradation products of HFO-1234ze(E) have negligible impact on the environment[3]. Compounds with short atmospheric lifetimes often contribute to the generation of tropospheric, or ground-level, ozone which is one of the components of photochemical smog. That is not the case with HFO-1234ze(E). The MIR (maximum incremental reactivity) and POCP (photochemical ozone creation potential) values for HFO-1234ze(E) have been determined to be 0.094 and 6.45, respectively. These very low values indicate that HFO-1234ze(E) has very low photochemical reactivity and does not contribute in any significant way to tropospheric ozone generation.

Table 6 shows the environmental properties of HFO-1234ze(E) compared to those of some commonly used propellants.

TABLE 6: ENVIRONMENTAL PROPERTIES OF MDI PROPELLANTS*

	HFO-1234ze(E)	HFA-152a	HFA-134a	HFA-227ea
GWP[6] (versus CO_2, 100 year ITH)	1.37	164	1530	3360
Atmospheric Lifetime (years)	0.04	1.4	13.8	33
VOC Status*	Exempt	Exempt	Exempt	Exempt

** The U.S. EPA has classified HFO-1234ze(E) as VOC-exempt.

COMPATIBILITY

HFO-1234ze(E) exhibits good compatibility with plastics, elastomers and metals. In storage tests, it has been shown to be compatible with aluminum aerosol cans, tin plate cans and PETlined cans. HFO-1234ze(E) has also been tested with aerosol valves and found to be compatible with common gasket materials including grades of butyl rubber, buna and neoprene. Since results may vary, it is always recommended that testing be done to confirm compatibility with specific package components and materials of construction. Metered Dose Inhaler (MDI) valve compatibility tests have been run by Aptar Pharma. Test information is available upon request.

STABILITY

HFO-1234ze(E) has been shown to be thermally and hydrolytically stable. In one experiment, samples of HFO-1234ze(E), in the presence of water and metals, were stored at 392°F (200°C) for two weeks. There was no observed effect on the metals and analysis showed no indication of breakdown of the HFO-1234ze(E). Also, samples stored in steel cylinders for several years have been analyzed and found to be within the specification.

TOXICITY

HFO-1234ze(E) has an extensive battery of toxicity studies that have been used to support FDA Investigational New Drug (IND) filings. Pre-clinical toxicity studies used to enable the IND included: acute inhalation exposure, repeated dose inhalation exposure, genotoxicity, and reproductive and developmental toxicity in multiple species. Additionally, two carcinogenicity studies in rats and mice have been completed in support of global MDI applications. In a human clinical study, HFO-1234ze(E) was not found to be a human skin sensitizer. The results of those studies concluded that HFO-1234ze(E) exhibited a good safety profile for its use in Metered Dose Inhalers as well as other drug delivery systems.

STORAGE AND HANDLING

HFO-1234ze(E) should be handled in a manner consistent with materials categorized as "liquefied gases under pressure." As illustrated by the vapor pressure data, HFO-1234ze(E) is a moderate pressure gas and containers (bulk storage tanks or packages) should be rated for the pressure of HFO-1234ze(E). HFO-1234ze(E), in approved containers, should be stored in a cool, well-ventilated area. HFO-1234ze(E) containers should neither be punctured or dropped, nor exposed to open flames, excessive heat or direct sunlight. Container valves should be tightly closed after use and when the container is empty. As with other fluorinated materials, HFO-1234ze(E) should not be mixed with oxygen at elevated pressures. Applications necessitating pressurization — exceeding the vapor pressure of HFO-1234ze(E) — should use dry nitrogen.

The Solstice safety data sheet (SDS) contains the most current and comprehensive information on the health, safety and environmental aspects of HFO-1234ze(E).

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5. Wallington, T.J., Sulbaek Andersen, M.P. and Nielsen, O.J.: Estimated photochemical ozone creation potentials (POCPs) of (HFO-1234yf) and related hydrofluoroolefins (HFOs), Atmospheric Environment, 44, 1478-1481, 2010.
6. IPCC Assessment Report 6

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